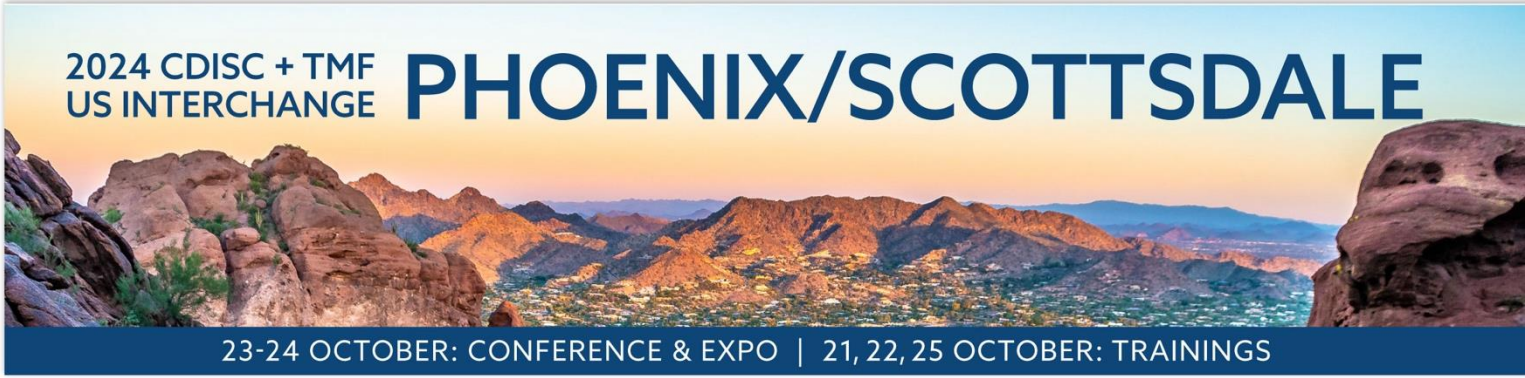

Advancing Clinical Trial Diversity: Beyond the Traditional Race Categories

Donna Sattler, Clinical Data Standards Strategic Leader
Sharon Hartpence, Associate Director, Clinical Data Standards, Bristol Myers Squibb,

Meet the Speakers

Donna Sattler

Title: Clinical Data Standards Strategy Leader
Organization: Open for Hire!

A transformative leader with over 22 years of experience in clinical data standards management, programming, clinical data standards strategies, and best practices. Proven track record of driving efficiency, quality, and productivity in cross-functional environments. A fierce advocate for improving pathways for the inclusion of underrepresented populations into clinical trials.

Sharon Hartpence

Title: Associate Director, Clinical Data Standards
Organization: Bristol Myers Squibb

As an RN, BSN, MBA who has worked in Pharmaceutical Research and Development for over 25 years. As a data collection specialist; I've developed clinical trial processes to streamline efficiencies for end-to-end users. I continue to increase my knowledge of CDISC implementation best practices by engaging in opportunities with CDISC collaboration initiatives

Brian Harris

Title: Standards Developer Senior Director
Organization: AstraZeneca

Over 25 years of industry experience working as a biostatistician and, most recently, as a standards developer for data collection, cleaning, analysis, and reporting. Over 12 years of volunteer experience on the CDISC ADaM team supporting ADaM conformance, questionnaire supplements, and recent updates to the implementation guide. Served as ADaM team lead in 2022 & 2023.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

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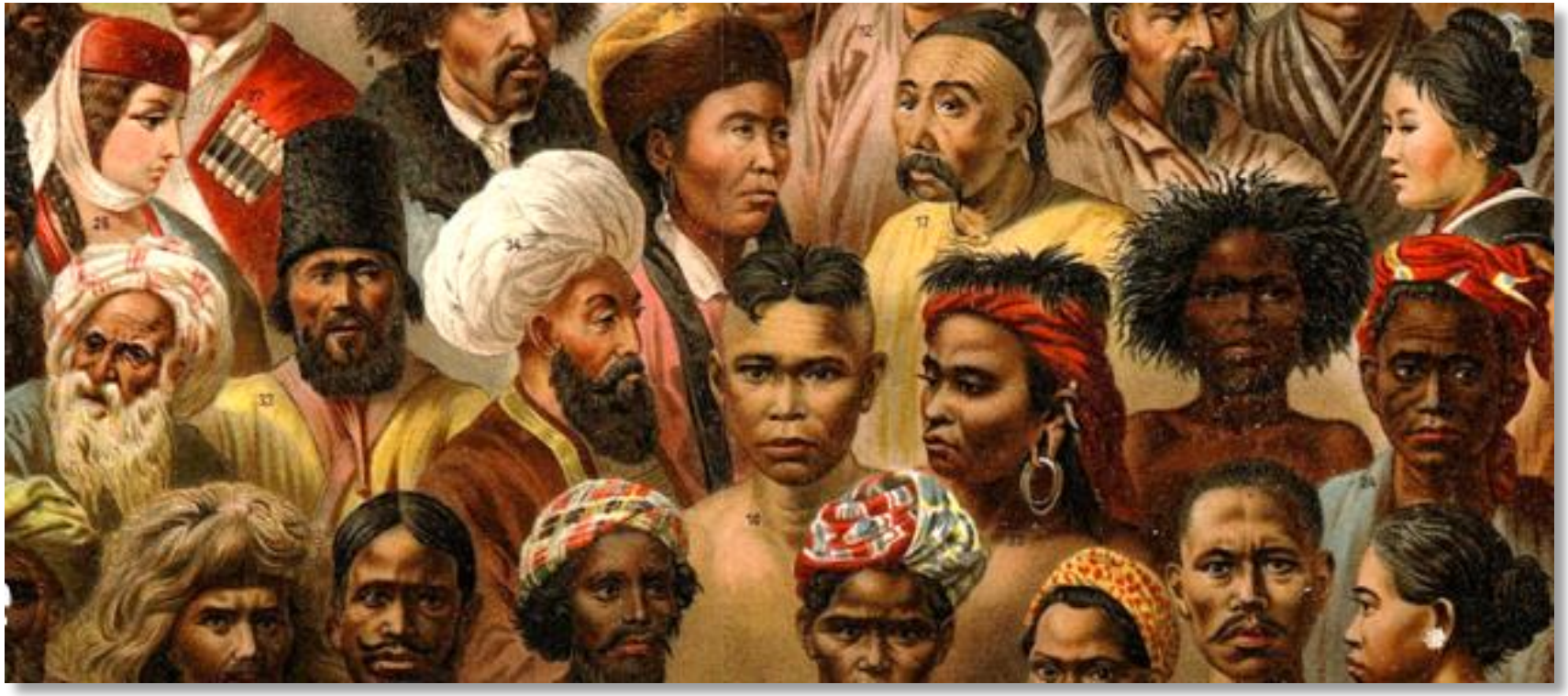
Agenda

1. History of RACE
2. Race in Clinical Research
3. Regulatory and Health Equity Pivot
4. Expanding Race Values/ Examples
5. Key Takeaways
6. Next Steps

History of Race



https://www.penn.museum/sites/pmclassroom/classes/understanding-the-history-of-race/

History of RACE data collection (US)

Census 1790, the sole purposes of this collection was for political representation and taxation:

- Three values represented the nation: free white people, all other free people & slaves.
- This data collection would go through several iterations of updates until most recent OMB recommendations in 2023 where five race values are suggested to expand to seven by combining ethnicity values and adding one.

Clinical Studies: complex history of discriminatory beliefs and practices

- The Tuskegee Syphilis Study in 1932 highlighted the need for ethical standards in CT
- Race collection has evolved to ensure diversity and equity in CT recognizing that different racial and ethnic groups may respond differently to treatments however it does not go far enough, we do more

The Lancet

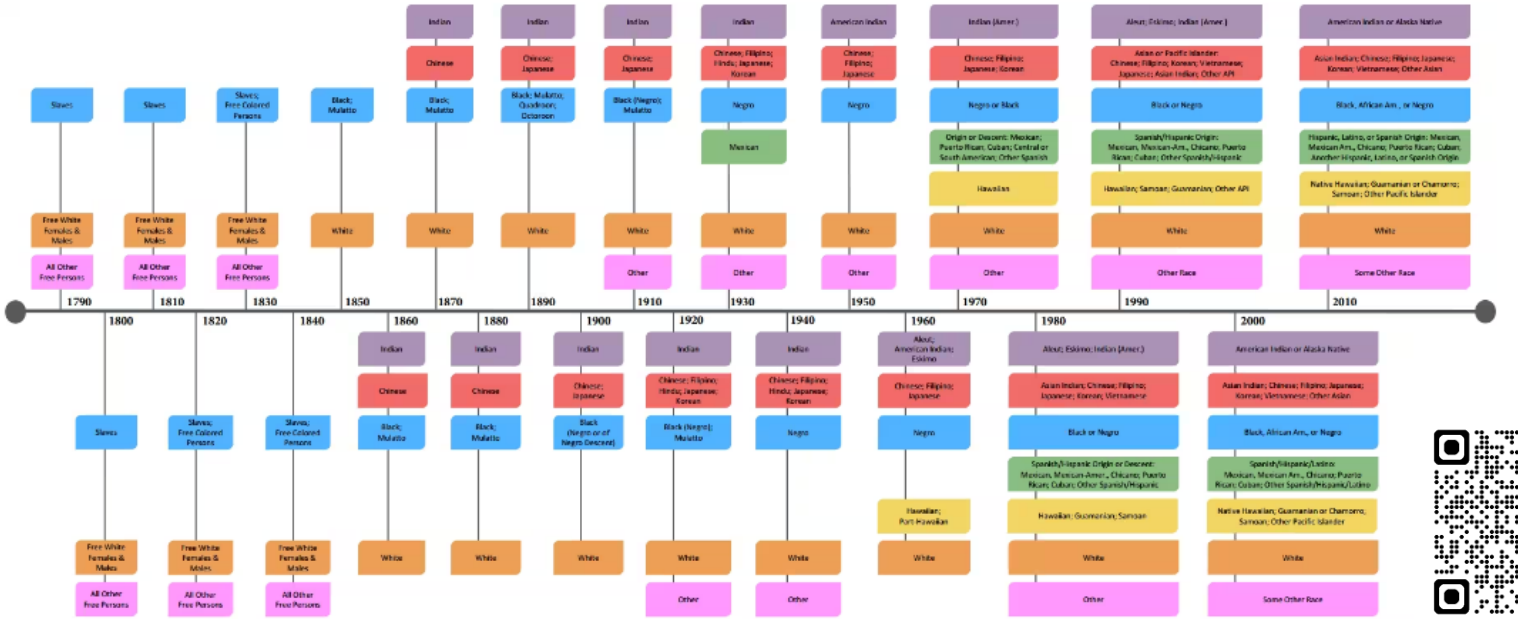
Harmonizing Global values

Here are the names of the generations over the last 120 years:

- **Greatest Generation**: Born 1901-1927
- **Silent Generation**: Born 1928-1945
- **Baby Boomers**: Born 1946-1964
- **Generation X**: Born 1965-1980
- **Millennials (Generation Y)**: Born 1981-1996
- **Generation Z**: Born 1997-2012
- **Generation Alpha**: Born 2013-2024
- **Generation Beta**: Born 2025-2039

These generational names help to categorize people based on shared cultural, social, and historical experiences.

One graphic traces how racial and ethnic labels in America have changed since 1790



(United States Census Bureau)

https://www.census.gov/data-tools/demo/race/MREAD_1790_2010.html

Harmonizing Global Race meanings

- **Country of Origin**: The country where a person was born or from which they emigrated.
- **Nativity**: Indicates whether a person was born in the country they currently reside (native-born) or in another country (foreign-born).
- **Race**: A group sharing physical characteristics like skin color and facial features.
- **Ethnicity**: A group sharing cultural heritage, language, religion, and traditions.
- **Generation**: Individuals born and living at about the same time, typically spanning 20-30 years.

Harmonizing Global Race values

Race data collection in clinical studies varies by country. Terms like “African American” may not be relevant in places like Nigeria or other African countries. Similarly, “White” or “Caucasian” may not apply in some regions. Local context and values should guide race data collection to ensure relevance and accuracy.

Africa:

- ❑ Black or African
- ❑ White
- ❑ Colored
- ❑ Asian
- ❑ Mixed or Multiracial
- ❑ Other ethnic groups

Australia:

- ❑ Aboriginal and Torres Strait Islander
- ❑ European
- ❑ Asian
- ❑ Middle Eastern or North African
- ❑ Pacific Islander
- ❑ Other ethnic group

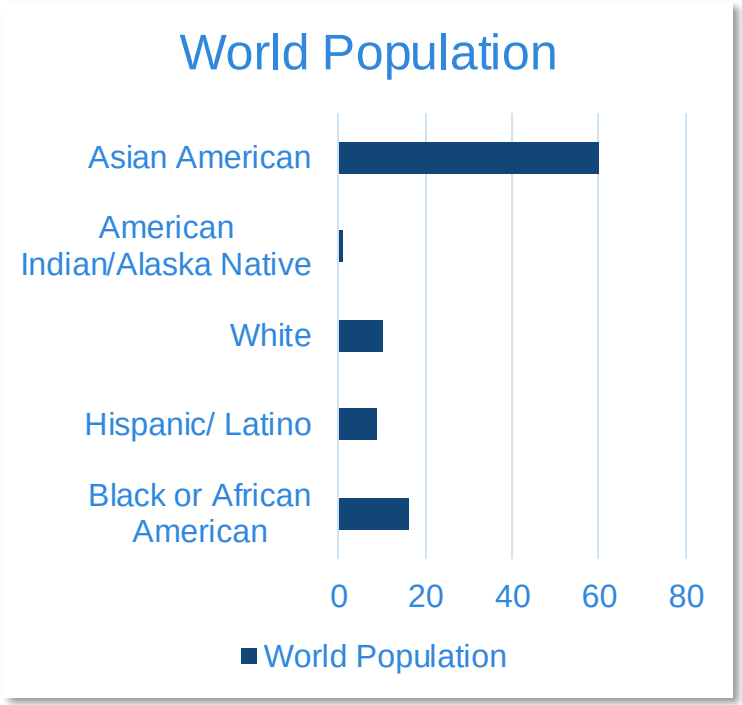
EU Union:

- ❑ White
- ❑ Black or African
- ❑ Asian
- ❑ Mixed or Multiple ethnic groups
- ❑ Other ethnic group

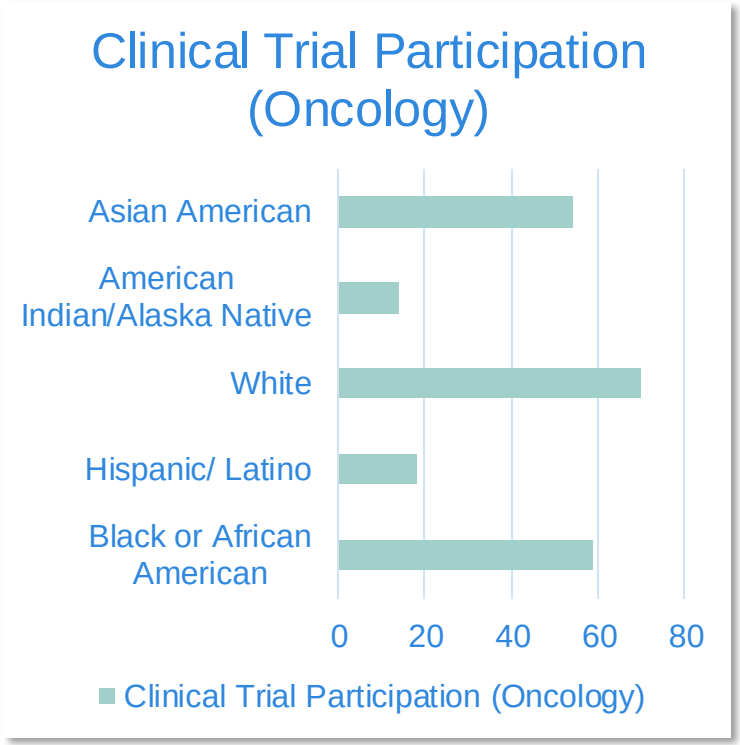
US:

- ❑ American Indian or Alaska Native
- ❑ Asian
- ❑ Black or African American
- ❑ Hispanic or Latino
- ❑ Middle Eastern or North African
- ❑ Native Hawaiian or Pacific Islander
- ❑ White

Race in Clinical Studies


World Population
Asian American
American Indian/Alaska Native
White
Hispanic/ Latino
Black or African American
0
20
40
60
80
World Population

VS


Clinical Trial Participation (Oncology)
Asian American
American Indian/Alaska Native
White
Hispanic/ Latino
Black or African American
0
20
40
60
80
Clinical Trial Participation (Oncology)

Disease Prevalence across Race/Ethnicity

Cardiovascular Disease (CVD)

1. **Black or African American**: Have the highest prevalence of hypertension, which increases the risk for heart disease and stroke. Heart disease mortality rates are significantly higher in Black Americans compared to whites.
2. **Hispanic/Latino**: Have lower rates of heart disease compared to whites, but a higher prevalence of conditions like diabetes that contribute to CVD.
3. **White**: Prevalence of heart disease is high but overall mortality rates from heart disease are lower than in Black populations.
4. **American Indian/Alaska Native**: Face higher risks for heart disease and hypertension compared to whites.
5. **Asian American**: Have lower overall CVD rates, but South Asians (e.g., Indians) have higher rates of heart disease compared to East Asians (e.g., Chinese, Japanese).

Rare Diseases and Race Prevalence

1. **Cystic Fibrosis (CF)**: More common among people of Northern European descent.
2. **Sickle Cell Disease**: Primarily affects individuals of African, Mediterranean, Middle Eastern, and Indian ancestry.
3. **Tay-Sachs Disease**: Higher prevalence among Ashkenazi Jews, French-Canadian, and Cajun populations.
4. **Alpha Thalassemia**: More prevalent in people of Southeast Asian, Mediterranean, and African descent.
5. **Familial Mediterranean Fever (FMF)**: Seen more frequently in people of Mediterranean, Middle Eastern, and North African backgrounds.

Rare diseases affect approximately 5% to 10% of the global population, but their prevalence and impact can vary significantly across racial and ethnic categories due to genetic factors, access to care, and underdiagnosis. Some rare diseases are more common in certain racial or ethnic groups

Using race to identify kidney disease; misses patients or identifies them too late for transplants….

The use of race in calculating kidney transplant eligibility has been prohibited since July 27, 2022. This change was made to ensure that all candidates are assessed equitably and to address disparities in access to transplantation.

	Explanation
Why the change was made	Race-inclusive calculations can inaccurately estimate kidney function for Black patients, which can delay their access to transplantation.
What the change means	Transplant hospitals must use race-neutral calculations to estimate a patient's kidney function.
What happens to patients who were affected	Kidney transplant programs must assess their waiting lists and correct the waiting times of any Black patients who were disadvantaged by the previous calculations.

…eGFR formulas include a race variable for people identified as Black…more muscle mass throws off the calculation….

Regulatory and Health Equity Pivot

Expanded Race Categories: better science for all.
The argument…granular RACE data will not have statistical significance…..so why bother?

Health Disparities

Ethical Considerations

Importance of Precision in Data Collection

Personalized Medicine

Regulatory Requirements and Standards

Public Health and Policy Implications

Reluctance for new implementation

- Multiple Race values cause special downstream processing consideration for reporting out to regulatory, can lead to messy data
- Unknown, not reported or “other” options lead to messy data
- Hesitation to collect small amounts of data that will be “Not clinically significant”
  - Short-term issue until this becomes more of the the norm
- Electronic Health Records (EHR) are used to pull in demographic data instead of self reporting

Help Overcome Implementation Problems

Challenges

- Complexity of categorization: Some individuals may not identify with standard categories.
- Risk of stigmatization or misuse of data.
- Balancing privacy concerns with the need for detailed demographic information.

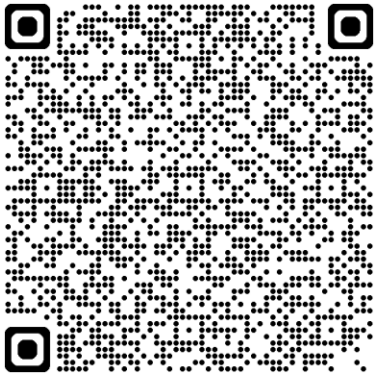
Overcoming Challenges

- Ensure voluntary, self-identified race categories; provide clear definitions and options for multi-racial individuals.
- Increase public trust by safeguarding data privacy.
- Continued training and education for researchers on the importance of race data.

Expanding Race Values/ Examples

OMB Recommendations:

1. Combining Race and Ethnicity values
2. Removing – Ethnicity as a separate question
3. Revising – definitions of each value
4. Adding Hispanic or Latino and Middle Eastern or North African



OMB Publishes Revisions to Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity | OMB | The White House

CRF Examples: Proposal

Which of the seven racial designations best describes you? (More than one choice is acceptable)

- ❑ American Indian or Alaska Native
- ❑ Asian
- ❑ Black or African American
- ❑ **Hispanic or Latino**
- ❑ **Middle Eastern or North African**
- ❑ Native Hawaiian or Other Pacific Islander
- ❑ White

- ❑ Not reported
- ❑ Unknown
- ❑ Other

What was the other race? _____

If American Indian or Alaska Native Subcategory:

DM.RACE and SUPPDM.RACE1 and/or SUPPDM.RACE2 and/or …RACE5

If "Other", DM.RACE and SUPPDM.RACEOTH

If RACE = American Indian or Alaska Native; SUPPDM.CRACE = "ESKIMO"

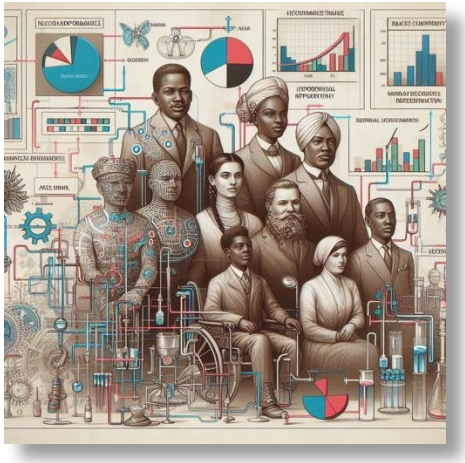
Example Output for Race and Ethnicity Combined

RACE/Ethnicity		TRT1
Race/Ethnicity RACETH	n (%)	xxx (xx.x)
Asian	n (%)	xxx (xx.x)
CRACE <<crace, cethnicity>>	n (%)	xxx (xx.x)
Black or African	n (%)	xxx (xx.x)
CRACE <<crace, cethnicity>>	n (%)	xxx (xx.x)
Hispanic or Latino	n (%)	xxx (xx.x)
Indigenous	n (%)	xxx (xx.x)
Native Hawaiian or Other Pacific Islander	n (%)	xxx (xx.x)
White	n (%)	xxx (xx.x)
Middle Eastern North African	n (%)	xxx (xx.x)
Multiple	n (%)	xxx (xx.x)
<<race>> / <<race>>	n (%)	xxx (xx.x)
<<race>> / <<race>> / <<race>>	n (%)	xxx (xx.x)
Other	n (%)	xxx (xx.x)
Missing	n (%)	xxx (xx.x)

Key Takeaways

Why Race category expansion matters

- Expanded race categories are essential for enhancing the accuracy and equity of clinical trials.
- They contribute to personalized medicine, address health disparities, and support better public health policies.
- Ultimately, they help ensure that new treatments are safe and effective for all racial groups.



https://www.ncbi.nlm.nih.gov/books/NBK25522/

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-action-plans-improve-enrollment-participants-underrepresented-populations-clinical-studies

Considerations when setting enrollment goals

Clinical trial diversity helps ensure that clinical studies appropriately test the product in a representative sample of the product's intended use population.

- **demographic characteristics** (e.g., race, ethnicity, sex, age group)
- **clinical characteristics** (e.g., presence of comorbidities, disease etiology), and
- **other characteristics** (e.g., access to standard preventive and diagnostic care, access to standard treatments of the clinically relevant population).

Next Steps

CDISC Demographic Race Sub Team

CALL TO ACTION

dsattler0716@gmail.com

https://www.cdisc.org/volunteer/form


Thank you!